

IN THE CLAIMS

Please replace the claims as filed with the claims set forth below. This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Currently amended) A device for producing a condensation aerosol comprising
(a) a chamber comprising an upstream opening and a downstream opening, the openings allowing gas to flow therethrough

(b) a heat-conductive substrate, the substrate located at a position between the upstream and downstream openings,

(c) a drug composition film on the substrate, the film comprising a therapeutically effective dose of a drug when the drug is administered in aerosol form

(d) a heat source for supplying heat to said substrate to produce a substrate temperature greater than 300°C, and to substantially volatilize the drug composition film from the substrate in a period of 2 seconds or less, and

(e) means for producing an air flow across the substrate producing aerosol particles by condensation,

wherein the device produces a condensation aerosol containing ~~less than~~ about 10% or less by weight drug composition degradation products and at least 50% of the drug composition of said film.

2. (Original) The device of Claim 1, further comprising a mechanism for initiating said heat source.

3. (Original) The device of Claim 1, wherein said substrate has an impermeable surface.

4. (Original) The device of Claim 1, wherein said substrate has a contiguous surface area of greater than 1 mm² and a material density of greater than 0.5 g/cc.

5. (Original) The device of Claim 1, wherein the film has a thickness between 0.05 and 20 microns.

6. (Currently Amended) The device of Claim 5, wherein the thickness of the film is selected to allow the drug composition to volatilize from the substrate with ~~less than~~ about 5% or less by weight drug composition degradation products.

7. (Original) The device of Claim 6, wherein the drug composition is one that when vaporized from a film on an impermeable surface of a heat conductive substrate, the aerosol exhibits an increasing level of drug composition degradation products with increasing film thicknesses.

8. (Original) The device of Claim 5, wherein said drug composition comprises a drug selected from the group consisting of the following, and a film thickness within the range disclosed for said drug:

- (1) alprazolam, film thickness between 0.1 and 10 μm ;
- (2) amoxapine, film thickness between 2 and 20 μm ;
- (3) atropine, film thickness between 0.1 and 10 μm ;
- (4) bumetanide film thickness between 0.1 and 5 μm ;
- (5) buprenorphine, film thickness between 0.05 and 10 μm ;
- (6) butorphanol, film thickness between 0.1 and 10 μm ;
- (7) clomipramine, film thickness between 1 and 8 μm ;
- (8) donepezil, film thickness between 1 and 10 μm ;
- (9) hydromorphone, film thickness between 0.05 and 10 μm ;
- (10) loxapine, film thickness between 1 and 20 μm ;
- (11) midazolam, film thickness between 0.05 and 20 μm ;
- (12) morphine, film thickness between 0.2 and 10 μm ;
- (13) nalbuphine, film thickness between 0.2 and 5 μm ;
- (14) naratriptan, film thickness between 0.2 and 5 μm ;
- (15) olanzapine, film thickness between 1 and 20 μm ;
- (16) paroxetine, film thickness between 1 and 20 μm ;
- (17) prochlorperazine, film thickness between 0.1 and 20 μm ;
- (18) quetiapine, film thickness between 1 and 20 μm ;
- (19) sertraline, film thickness between 1 and 20 μm ;

- (20) sibutramine, film thickness between 0.5 and 2 μm ;
- (21) sildenafil, film thickness between 0.2 and 3 μm ;
- (22) sumatriptan, film thickness between 0.2 and 6 μm ;
- (23) tadalafil, film thickness between 0.2 and 5 μm ;
- (24) vardenafil, film thickness between 0.1 and 2 μm ;
- (25) venlafaxine, film thickness between 2 and 20 μm ;
- (26) zolpidem, film thickness between 0.1 and 10 μm ;
- (27) apomorphine HCl, film thickness between 0.1 and 5 μm ;
- (28) celecoxib, film thickness between 2 and 20 μm ;
- (29) ciclesonide, film thickness between 0.05 and 5 μm ;
- (30) eletriptan, film thickness between 0.2 and 20 μm ;
- (31) parecoxib, film thickness between 0.5 and 2 μm ;
- (32) valdecoxib, film thickness between 0.5 and 10 μm ;
- (33) fentanyl, film thickness between 0.05 and 5 μm .

9. (Original) The device of Claim 1, wherein said heat source substantially volatilizes the drug composition film from the substrate within a period of less than 0.5 seconds.

10. (Original) The device of Claim 1, wherein said heat source comprises an ignitable solid chemical fuel disposed adjacent to an interior surface of the substrate, wherein the ignition of said fuel is effective to vaporize the drug composition film.

11. (Original) The device of Claim 1, wherein said heat source for supplying heat to said substrate produces a substrate temperature greater than 350°C.

12. (Original) A method for producing a condensation aerosol comprising

(a) heating to a temperature greater than 300°C a heat-conductive substrate having a drug composition film on the surface, the film comprising a therapeutically effective dose of a drug when the drug is administered in aerosol form;

(b) substantially volatilizing the drug composition film from the substrate in a period of 2 seconds or less, and

(c) flowing air across the volatilized drug composition, under conditions to produce a condensation aerosol containing less than 10% by weight drug composition degradation products and at least 50% of the drug composition in said film.

13. (Original) The method of Claim 12, wherein said substrate has an impermeable surface.

14. (Original) The method of Claim 12, wherein said substrate has a contiguous surface area of greater than 1 mm² and a material density of greater than 0.5 g/cc.

15. (Original) The method of Claim 12, wherein the film has a thickness between 0.05 and 20 microns.

16. (Currently Amended) The method of Claim 15, wherein the thickness of the film is selected to allow the drug composition to volatilize from the substrate with ~~less than~~ about 10% or less by weight drug composition degradation products.

17. (Original) The method of Claim 16, wherein the drug composition is one that when vaporized from a film on an impermeable surface of a heat conductive substrate, the aerosol exhibits an increasing level of drug composition degradation products with increasing film thicknesses.

18. (Original) The method of Claim 12, wherein said drug composition comprises a drug selected from the group consisting of the following, and a film thickness within the range disclosed for said drug:

- (1) alprazolam, film thickness between 0.1 and 10 µm;
- (2) amoxapine, film thickness between 2 and 20 µm;
- (3) atropine, film thickness between 0.1 and 10 µm;
- (4) bumetanide film thickness between 0.1 and 5 µm;
- (5) buprenorphine, film thickness between 0.05 and 10 µm;
- (6) butorphanol, film thickness between 0.1 and 10 µm;

- (7) clomipramine, film thickness between 1 and 8 μm ;
- (8) donepezil, film thickness between 1 and 10 μm ;
- (9) hydromorphone, film thickness between 0.05 and 10 μm ;
- (10) loxapine, film thickness between 1 and 20 μm ;
- (11) midazolam, film thickness between 0.05 and 20 μm ;
- (12) morphine, film thickness between 0.2 and 10 μm ;
- (13) nalbuphine, film thickness between 0.2 and 5 μm ;
- (14) naratriptan, film thickness between 0.2 and 5 μm ;
- (15) olanzapine, film thickness between 1 and 20 μm ;
- (16) paroxetine, film thickness between 1 and 20 μm ;
- (17) prochlorperazine, film thickness between 0.1 and 20 μm ;
- (18) quetiapine, film thickness between 1 and 20 μm ;
- (19) sertraline, film thickness between 1 and 20 μm ;
- (20) sibutramine, film thickness between 0.5 and 2 μm ;
- (21) sildenafil, film thickness between 0.2 and 3 μm ;
- (22) sumatriptan, film thickness between 0.2 and 6 μm ;
- (23) tadalafil, film thickness between 0.2 and 5 μm ;
- (24) vardenafil, film thickness between 0.1 and 2 μm ;
- (25) venlafaxine, film thickness between 2 and 20 μm ;
- (26) zolpidem, film thickness between 0.1 and 10 μm ;
- (27) apomorphine HCl, film thickness between 0.1 and 5 μm ;
- (28) celecoxib, film thickness between 2 and 20 μm ;
- (29) ciclesonide, film thickness between 0.05 and 5 μm ;
- (30) eletriptan, film thickness between 0.2 and 20 μm ;
- (31) parecoxib, film thickness between 0.5 and 2 μm ;
- (32) valdecoxib, film thickness between 0.5 and 10 μm ; and
- (33) fentanyl, film thickness between 0.05 and 5 μm .

19. (Original) The method of Claim 12, wherein said substantially volatilizing the film is complete within a period of less than 0.5 seconds.

20. (Original) An assembly for use in a condensation aerosol device comprising

- (a) a heat-conductive substrate having an interior surface and an exterior surface;
- (b) a drug composition film on the substrate exterior surface, the film comprising a therapeutically effective dose of a drug when the drug is administered in aerosol form, and
- (c) a heat source for supplying heat to said substrate to produce a substrate temperature greater than 300°C and to substantially volatilize the drug composition film from the substrate in a period of 2 seconds or less.

21. (Original) The assembly of Claim 20, wherein said substrate has an impermeable surface.

22. (Original) The assembly of Claim 20, wherein said substrate surface has a contiguous surface area of greater than 1 mm² and a material density of greater than 0.5 g/cc.

23. (Original) The assembly of Claim 20, wherein the film has a thickness between 0.05 and 20 microns.

24. (Original) The assembly of Claim 23, wherein the thickness of the film is selected to allow the drug composition to volatilize from the substrate with ~~less than~~ about 5% or less by weight drug composition degradation products.

25. (Original) The assembly of Claim 24, the drug composition is one that when vaporized from a film on an impermeable surface of a heat conductive substrate, the aerosol exhibits an increasing level of drug composition degradation products with increasing film thickness.

26. (Original) The assembly of Claim 20, wherein said drug composition comprises a drug selected from the group consisting of the following, and a film thickness within the range disclosed for said drug:

- (1) alprazolam, film thickness between 0.1 and 10 µm;
- (2) amoxapine, film thickness between 2 and 20 µm;

- (3) atropine, film thickness between 0.1 and 10 µm;
- (4) bumetanide film thickness between 0.1 and 5 µm;
- (5) buprenorphine, film thickness between 0.05 and 10 µm;
- (6) butorphanol, film thickness between 0.1 and 10 µm;
- (7) clomipramine, film thickness between 1 and 8 µm;
- (8) donepezil, film thickness between 1 and 10 µm;
- (9) hydromorphone, film thickness between 0.05 and 10 µm;
- (10) loxapine, film thickness between 1 and 20 µm;
- (11) midazolam, film thickness between 0.05 and 20 µm;
- (12) morphine, film thickness between 0.2 and 10 µm;
- (13) nalbuphine, film thickness between 0.2 and 5 µm;
- (14) naratriptan, film thickness between 0.2 and 5 µm;
- (15) olanzapine, film thickness between 1 and 20 µm;
- (16) paroxetine, film thickness between 1 and 20 µm;
- (17) prochlorperazine, film thickness between 0.1 and 20 µm;
- (18) quetiapine, film thickness between 1 and 20 µm;
- (19) sertraline, film thickness between 1 and 20 µm;
- (20) sibutramine, film thickness between 0.5 and 2 µm;
- (21) sildenafil, film thickness between 0.2 and 3 µm;
- (22) sumatriptan, film thickness between 0.2 and 6 µm;
- (23) tadalafil, film thickness between 0.2 and 5 µm;
- (24) vardenafil, film thickness between 0.1 and 2 µm;
- (25) venlafaxine, film thickness between 2 and 20 µm;
- (26) zolpidem, film thickness between 0.1 and 10 µm;
- (27) apomorphine HCl, film thickness between 0.1 and 5 µm;
- (28) celecoxib, film thickness between 2 and 20 µm;
- (29) ciclesonide, film thickness between 0.05 and 5 µm;
- (30) eletriptan, film thickness between 0.2 and 20 µm;
- (31) parecoxib, film thickness between 0.5 and 2 µm;
- (32) valdecoxib, film thickness between 0.5 and 10 µm; and
- (33) fentanyl, film thickness between 0.05 and 5 µm.

27. (Original) The assembly of Claim 20, wherein said heat source substantially volatilizes the drug composition film from the substrate within a period of less than 0.5 seconds.

28. (Original) The device of Claim 20, wherein said heat source comprises an ignitable solid chemical fuel disposed adjacent to the interior surface of the substrate, wherein the ignition of said fuel is effective to vaporize the drug composition film.